FUJIFILM

MAY 16 2011

FUJIFILM GROUP
FUJINON INC.
10 High Point Drive
Wayne, NJ 07470
Tel: (973) 633-5600

K111243
Page 1 of 2

510(k) Summary

Date: April 14, 2011

Submitter's Information:

Fujinon Inc.
10 High Point Drive
Wayne, NJ 07470 USA

Contact Person:

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Title: Director, Quality and Regulatory Compliance
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Identification of the Proposed Device:

Proprietary/Trade Name: Fujinon Ultrasonic Processor SU-8000
Common Name: Ultrasonic Processor for Ultrasonic Gastrointestinal Endoscopy
Device Class: Class 2
Classification Information:

Classification Name	CFR Section	Product Codes
Gastroscope	21 CFR 876.1500	FDS
Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550	IYN
Ultrasonic Pulsed Eco Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasonic Transducer	21 CFR 892.1570	ITX

I. INDICATIONS FOR USE

The Fujinon ultrasonic processor SU-8000 is intended to be used in combination with Fujinon/Fujifilm ultrasonic endoscope, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, recording and to aid in diagnosis during endoscopic evaluation.

II. DEVICE DESCRIPTION

Fujinon Ultrasonic Processor SU-8000 is a new ultrasonic processor, which can be used with the previously-cleared ultrasonic gastrointestinal endoscopes, EG-530UR and EG-590UT via K063847.

Fujinon Ultrasonic Processor SU-8000 consists of a scan engine and a function box and SU-8000 is controlled by keyboard (model: CP-8000) SU-8000 connects to ultrasonic endoscopes, which emits ultrasound in a body cavity by driving ultrasonic transducers of

the endoscope. SU-8000 also processes the reflection of ultrasonic signals received by the transducer and converts it to an ultrasound image.

SU-8000 is used in combination with ultrasonic endoscopes, video processor, light source, cart, recorder, foot switch and other peripheral devices (e.g. external monitor and printer), which is the same as the legally marketed device, SU-7000.

III. SUMMARY OF STUDIES

Fujinon Ultrasonic Processor (SU-8000) was evaluated in accordance with following safety and performance requirements in addition to the applicable quality system regulations:

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC60601-1-2	Medical electrical equipment - Part 1-2: General requirements for the basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
IEC 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

No clinical test was conducted.

IV. SUBSTANTIAL EQUIVALENCE

Fujinon Ultrasonic Processor SU-8000 is substantially equivalent to the following device:

Legally Marketed Device	510(k) #
Fujinon Ultrasonic Endoscope & Processor (EG-530UR, EG-530UT with SU-7000)	K063847

The proposed device, Fujinon Ultrasonic Processor SU-8000 has the same Indications for Use and very similar Functional and Technical requirements as our legally marketed device, Ultrasonic Processor (SU-7000) via K063847.

V. CONCLUSION

Fujinon Ultrasonic Processor SU-8000 is substantially equivalent to the legally marketed device and conforms to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fujinon, Inc.
c/o Mr. Mark Job
Regulatory Affairs Specialist
Regulatory Technology Services, Inc.
1394 25th Street, N.W.
BUFFALO MN 55313

MAY 16 2011

Re: K111243
Trade/Device Name: Fujinon Ultrasonic Processor SU-8000
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS, IYN, IYO and ITX
Dated: May 2, 2011
Received: May 3, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Fujinon Ultrasonic Processor SU-8000, as described in your premarket notification:

Transducer Model Number

EG-530UR and EG-530UT

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Mary Beth O'Brien, M.S.R.N., at (301) 796-6657.

Sincerely yours,

for Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

K111243

Indications For Use Statement

510(k) Number (If Known): K111243

Device Name: Fujinon Ultrasonic Processor SU-8000

Indications for Use:

The ultrasonic processor (SU-8000) is intended to be used in combination with Fujinon/Fujifilm ultrasonic endoscope, video processor, light source, monitor, recorder, and various peripheral devices. The product is intended to provide ultrasonic images of submucosal and peripheral organs of the upper gastrointestinal tract for observation, recording and to aid in diagnosis during endoscopic evaluation.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111243

K111243

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): K111243

System Name: Fujinon Ultrasonic Processor SU-8000

Transducer: With All Ultrasonic Endoscopes (EG-530UR and EG-530UT)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler	Combined[1]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)	N	N	N		N	N[1]	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)[2]	N	N	N		N	N[1]	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P = previously cleared by FDA; E = added under this appendix

[1] Combined modes includes B+M, B+PWD, B+CD+PWD modes
[2] Other includes gastro-intestinal tract and surrounding organs

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111243

Prescription Use ✓
(Per 21 CFR 801.109)

K111243

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): K111243

System Name: Fujinon Ultrasonic Processor SU-8000

Transducer: Ultrasonic Endoscope (EG-530UT)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler	Combined[1]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)	N	N	N		N	N[1]	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)[2]	N	N	N		N	N[1]	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111243

Prescription Use ✓
(Per 21 CFR 801.109)

K111243

Diagnostic Ultrasound Indications For Use

510(k) Number (If Known): K111243

System Name: Fujinon Ultrasonic Processor SU-8000

Transducer: Ultrasonic Endoscope (EG-530UR)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler	Combined[1]	Other
Ophthalmic	Ophthalmic							
General Application	Fetal							
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Tran-esoph. (non-Card.)	N	N	N		N	N[1]	
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)[2]	N	N	N		N	N[1]	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Tran-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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